OCT 1 1 2005

K05912

3 510(k) Summary

510(k) SUMMARY FOR ALSIUS CORPORTATION'S COOLGARD AND CATHETER THERMAL REGULATION SYSTEM

Submitter's Name, Address, Telephone Number, and Contact Person:

ALSIUS CORPORATION
15770 Laguna Canyon Road, Suite 150
Irvine, CA 92618

Contact: Ken Collins
Phone: 949-453-0150
Fax: 949-453-0250
Email: kcollins@alsius.com

Name of Device:

The Alsius CoolGard And Catheter Thermal Regulation System.

Common or Usual Name:

Central Venous Catheter (short term) and Thermal Regulating System.

Classification Name:

FDA has classified the Alsius CoolGard/Catheter system for various indications as a Class II device under 21 C.F.R. § 870.5900.

Indications for Use

Cool Line Cathers - Indications for Use:

The Alsius CoolGard® 3000 and Cool Line ™ Catheter Thermal Regulation System is indicated for use in fever reduction, as an adjunct to other antipyretic therapy, in patients with cerebral infarction and intracerebral hemorrhage who require access to the central venous circulation and who are intubated and sedated.

Warning – Fever Reduction

The safety of this device has not been demonstrated for fever reduction in patients presenting with subarrachnoid hemorrhage or primary traumatic brain injury. The safety and effectiveness of this device was examined in a randomized controlled trial of 296 patients. The mortality results reported in this trial, for the four patient cohorts enrolled, are presented in the table below (CI – cerebral infarction, ICH – intracerebral hemorrhage, PTBI – primary traumatic brain injury, SAH – subarrachnoid hemorrhage).

Mortality by Diagnosis (ITT analysis)

	Cool Line			Control			
	n	N	%	n	N	%	p*
CI	3	16	18.8	3	14	21.4	0.74
ICH	8	33	24.2	7	27	25.9	1.00
PTBI	10	44	22.7	4	38	10.5	0.24
SAH	13	61	21.3	7	63	11.1	0.15

*Fischer's exact test

For more details on the clinical trial results please refer to Physician's Manual – "Normothermia for the Neuro-critically Ill stroke patient" #101416-001.

Fortius and Icy Catheters - Indications for Use:

The COOLGARD™ 3000/Alsius Catheter Thermal Regulation System, using either the Icy™ or Fortius™ model catheter, is indicated for use:

- in cardiac surgery patients to achieve and or maintain normothermia during surgery and recovery/intensive care, and
- to induce, maintain and reverse mild hypothermia in neurosurgery patients in surgery and recovery/intensive care.

Summary of the Basis for Finding of Substantial Equivalence:

This submission relates to the addition of labeling relating to the use of the Alsius Cool Line®, Icy® and Fortius® Catheters in an MRI environment.

The predicate devices for this change in labeling are the catheters themselves as cleared under the following 510(k): K030421 (Fortius and ICY) and K014241 (Cool Line).

The labeling of these catheters is otherwise unchanged.

Conclusion

In summary, descriptive information and performance data demonstrate that the Alsius CoolGard and Catheter Thermal Regulation System characteristics do not raise new questions of safety and effectiveness. Where appropriate, performance data demonstrate equivalence. The CoolGard system is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2005

Kenneth A. Collins, M.D.
Vice President Clinical/Quality/Regulatory
Alsius Corporation
15770 Laguna Canyon, Road, Suite 150
Irvine, California 92618

Re: K051912
Trade/Device Name: Alsius Cool Line, Icy & Fortius Heat Exchange Catheters
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: Class II
Product Code: NCX
Dated: September 20, 2005
Received: September 21, 2005

Dear Dr. Collins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that the Cool Line Catheter will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling as a box warning immediately following the indications for use statement:

The safety of this device has not been demonstrated for fever reduction in patients presenting with subarrachnoid hemorrhage or primary traumatic brain injury. The safety and effectiveness of this device was examined in a randomized controlled trial of 296 patients. The mortality results reported in this trial, for the four patient cohorts enrolled, are presented in the table below (CI – cerebral infarction, ICH – intracerebral hemorrhage, PTBI – primary traumatic brain injury, SAH – subarrachnoid hemorrhage).

Mortality by Diagnosis (ITT)

	Cool Line			Control			
	n	N	%	n	N	%	p-value*
CI	3	16	18.8	3	14	21.4	0.74
ICH	8	33	24.2	7	27	25.9	1.00
PTBI	10	44	22.7	4	38	10.5	0.24
SAH	13	61	21.3	7	63	11.1	0.15

*Fischer's exact test

For more details on the results of this study please refer to Physician's Manual – "Normothermia for the Neuro-critically Ill stroke patient" #101416-001.

Please note that the above labeling limitation is required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before this limitation is modified in any way or removed from the device's labeling. This limitation does not apply to the Icy & Fortius Catheters.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051912

Device Name: CoolGard and Catheter Thermal Regulation System

Indications For Use:

Fortius and Icy Catheters - Indications for Use:

The COOLGARD™ 3000/Alsius Catheter Thermal Regulation System, using either the Icy™ or Fortius™ model catheter, is indicated for use:

- in cardiac surgery patients to achieve and or maintain normothermia during surgery and recovery/intensive care, and
- to induce, maintain and reverse mild hypothermia in neurosurgery patients in surgery and recovery/intensive care.

Prescription Use _X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Indications for Use

510(k) Number (if known): K051912

Device Name: CoolGard and Catheter Thermal Regulation System

Indications For Use:

Cool Line Cathers - Indications for Use:

The Alsius CoolGard® 3000 and Cool Line ™ Catheter Thermal Regulation System is indicated for use in fever reduction, as an adjunct to other antipyretic therapy, in patients with cerebral infarction and intracerebral hemorrhage who require access to the central venous circulation and who are intubated and sedated.

Warning – Fever Reduction

The safety of this device has not been demonstrated for fever reduction in patients presenting with subarrachnoid hemorrhage or primary traumatic brain injury. The safety and effectiveness of this device was examined in a randomized controlled trial of 296 patients. The mortality results reported in this trial, for the four patient cohorts enrolled, are presented in the table below (CI – cerebral infarction, ICH – intracerebral hemorrhage, PTBI – primary traumatic brain injury, SAH – subarrachnoid hemorrhage).

Mortality by Diagnosis (ITT analysis)

	Cool Line			Control			
	n	N	%	n	N	%	p*
CI	3	16	18.8	3	14	21.4	0.74
ICH	8	33	24.2	7	27	25.9	1.00
PTBI	10	44	22.7	4	38	10.5	0.24
SAH	13	61	21.3	7	63	11.1	0.15

*Fischer's exact test

For more details on the clinical trial results please refer to Physician's Manual – "Normothermia for the Neuro-critically Ill stroke patient" #101416-001.

Prescription Use _X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K051912